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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,004	05/10/2007	Thomas Koehler	PHDE040056US	8994

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EXAMINER	
HOFFA, ANGELA MARIE	
ART UNIT	PAPER NUMBER
3768	
MAIL DATE	DELIVERY MODE
05/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,004	KOEHLER ET AL.	
	Examiner	Art Unit	
	Angela M. Hoffa	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to communication filed on May 10, 2007.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Drawings

3. The drawings are objected to because Figures 2 and 4 includes boxes 27, 23, and 152 that are not properly labeled. References numerals alone are considered to be insufficient.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to for omitting section headings outlined below. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

5. Claim 11 is objected to because of the following informalities: The claim appears to be directed towards a method of using containers but merely states "use of containers" as the subject matter of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,475,148 to *Jackson et al*.

Jackson et al discloses using a computer program to evaluate a heart beat rate of a heart of a patient, triggering a rupturing of a container comprising a drug on the basis of the evaluation of the heart beat rate (trigger device 26, Fig. 1, Col. 3 Lines 38-51), wherein the container is located in proximity to the part of the body resulting in a local application of the drug to the part of the body (Col. 3, Lines 29-37).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,628,981 to *Baker et al* in view of the article titled "Noninvasive Visualization of Coronary Arteries Using Contrast-Enhanced Multidetector CT" to *Giesler et al* in further view of U.S. Patent No. 6,475,148 to *Jackson et al*.

Baker et al discloses imaging a patient during a CT scan (Fig. 1), monitoring the heart beat rate of the patient (EKG 46, Fig. 2), and correlating the imaging procedure with the heart beat rate of the patient (Sync Unit 48, Fig. 2). *Baker et al* further discloses the importance of having a steady and predictable heartbeat during a CT scan in order to reduce motion artifacts (Col. 2, Lines 1-30).

However, *Baker et al* does not disclose using containers to deliver drugs to the patient or applying drugs to the patient to control his heart rate.

Giesler et al discloses a CT imaging procedure in which accuracy of cardiac imaging increases as the heart rate decreases. To decrease the heart rate, a drug is given to the patient (Conclusion section and Page 912, Col. 1, Lines 6-10).

Jackson et al discloses wherein drug-containing microbubbles are burst with ultrasonic waves in the heart (Col. 1, Lines 19-25, Col. 7, Line 31) in order to selectively deliver drugs for treatment (Col. 1, Line 66 – Col. 2, line 21).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an ultrasound microbubble technique to deliver drugs to slow a patient's heart during a CT scan ultrasound procedure in order to provide data with less motion artifact.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,628,981 to *Baker et al* in view of the article titled "Noninvasive Visualization of Coronary Arteries Using Contrast-Enhanced Multidetector CT" to *Giesler et al* in further view of U.S. Patent No. 6,475,148 to *Jackson et al* as applied to Claim 1 above, in further view of U.S. Patent No. 5,542,935 to *Unger et al.*

Baker et al in view of *Giesler et al* in further view of *Jackson et al* does not expressly disclose using two sets of microbubbles with different resonant frequencies.

However, *Unger et al* discloses a microbubble drug delivery system that uses different sized microbubbles in order to change the resonant frequency of the application (Col. 30, Lines 58-63).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple sets of microbubbles with different resonant properties, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8 and as taught by *Unger et al.*

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,628,981 to *Baker et al* in view of the article titled "Noninvasive Visualization of Coronary Arteries Using Contrast-Enhanced Multidetector CT" to *Giesler et al* in further view of U.S. Patent No. 6,475,148 to *Jackson et al* in further view of U.S. Patent No. 5,542,935 to *Unger et al* as applied to Claim 5 above, in further view of article "Control of Heart Rate" to *Kestin*.

Baker et al in view of *Giesler et al* in further view of *Jackson et al* in further view of *Unger et al* does not expressly disclose wherein application of drugs from the microbubble sets raises and lowers the patient's heart rate.

Baker et al discloses the importance of having a steady and predictable heartbeat during a CT scan in order to reduce motion artifacts (Col. 2, Lines 1-30), and *Giesler et al* discloses a CT imaging procedure in which accuracy of cardiac imaging increases as the heart rate decreases. To decrease the heart rate, a drug is given to the patient (Conclusion section and Page 912, Col. 1, Lines 6-10).

Furthermore, *Kestin* discloses types of drugs that are used to regulate heart rate by increasing or decreasing properties that cause the heart to beat (adrenaline, anesthetic drugs, first page).

Since *Unger et al* and *Jackson et al* disclose many types of drugs that can be encapsulated into microbubbles and ultrasonically burst when they reach the target area, it would be obvious to use drugs to raise and lower the heart rate of a patient in order to obtain a steady and predictable heart rate for CT imaging as taught by *Baker et al* (Col. 2, Lines 1-30).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 7,358,226 to *Dayton et al* discloses a microbubble drug delivery method that reads on the claimed invention. U.S. Patent No. 5,190,766 to *Ishihara* discloses using microbubbles to deliver drugs to a target area and reads on the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Hoffa whose telephone number is 571-270-7408. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M. H./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768